

Appl. No. 09/929,863  
Amdt. Dated August 21, 2003  
Reply to Office action of March 12, 2003

### REMARKS

Claims 1-7 and 10-14 are pending. Claims 1-7 and 10-14 are rejected. Claim 10 is cancelled, without prejudice. The specification is amended to properly indicate the issuance of a US patent. Claims 1, 2-4, 6, and 13-14 are amended. Support for amended Claim 1 can be found on page 3, lines 15-27. Amendments to Claims 2-4, 6, and 13-14 are supported on, e.g., page 9, lines 1-9; page 10, lines 22-28; page 12, lines 6-9, and page 13, lines 29-35, and page 14, lines 1-4, of the specification. New Claim 19 is added. Support for new Claim 19 can be found, e.g., on page 3, lines 15-27, of the specification.

Applicants believe that no new matter is added by the foregoing amendments.

Applicants acknowledge the Examiner's withdrawal of the objection to the specification, withdrawal of the rejection of Claims 15-18 under 35 U.S.C. §102(b), and withdrawal of the rejection of Claim 16 under 35 U.S.C. §112, second paragraph.

#### I. Rejections of Claims 1-7 and 11-14 under 35 U.S.C. §112, First Paragraph.

The Examiner maintained the rejection of Claims 1-7 and 11-14 under 35 U.S.C. §112, first paragraph. Claim 10 is cancelled and the rejection is moot as to these claims. The Examiner alleges that both IFN- $\alpha$  and a source of IL-10 are necessary for differentiation (page 3, lines 1-6, of Office Action). Amended Claim 1 recites a source of IL-10, thus removing the basis for rejection of Claims 1-7 and 11-14. Applicants also believe that new Claim 19 is free from this rejection as the specification states that cord blood T cells can differentiate to Tr1 cells in the presence of IFN- $\alpha$  alone (see, e.g., page 3, lines 15-27, of the specification).

Applicants believe the rejection of Claims 1-7 and 11-14 under 35 U.S.C. §112, first paragraph is overcome by the foregoing amendment. Withdrawal of this rejection is respectfully requested.

#### II. Rejections of Claims 1-7, 10, and 13, under 35 U.S.C. §102(b).

The Examiner rejected Claims 1-7, 10, and 13, under 35 U.S.C. §102(b), as being anticipated by WO 88/03411. Claim 10 is cancelled and the rejection is moot as

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to these claims. Applicants note that "Tr cells" are also known as "Treg cells" and "regulatory T cells."

The Examiner alleges that the claims encompass effects that are inherently practiced *in vivo* (page 3, lines 12, of Office Action). However, WO 88/03411 fails to teach use of any isolated or purified naïve CD4+ T cell precursor. Amended Claim 1 recites use of this isolated or purified T cell precursor. In view of the failure of the cited reference to teach use of an isolated or purified CD4+ T cell precursor, Applicants believe the cited reference fails to anticipate Claim 1, and Claims 2-7, 10, and 13, which depend from Claim 1. Applicants also believe that new Claim 19 is free from this basis of rejection, as WO 88/03411 fails to teach differentiation of an isolated or purified cord blood T cell to a Tr1 cell.

Applicants submit that the rejection of Claims 1-7, 10, and 13, under 35 U.S.C. §102(b) is overcome by the foregoing amendment. Withdrawal of this rejection is respectfully requested.

III. Rejections of Claims 1-7 and 10-13, under 35 U.S.C. §102(e).

The Examiner rejected Claims 1-7 and 10-13, under 35 U.S.C. §102(e), as being anticipated by U.S. Pat. No. 6,346,243 issued to Brod. Claim 10 is cancelled and the rejection is therefore moot as to these claim. The Examiner alleges that the claims encompass effects that are inherently practiced *in vivo* (page 4, lines 16-17, of Office Action). Applicants respectfully disagree. Brod fails to teach use of an isolated or purified CD4+ T cell precursor, as recited in amended Claim 1.

Furthermore, amended Claim 2 recites Tr1 cell is characterized by expression of high levels of IL-10, significant levels of TRG-β, and significant levels of IFN-γ. In contrast, the cited reference discloses that human patients treated with IFN-α show decreased IL-10, decreased IFN-γ, and decreased TGF-β (column 6, lines 5-9, of Brod). Thus, Brod teaches away from the present invention.

In view of the failure of Brod to teach use of an isolated or purified a naïve CD4+ T cell precursor as well as the failure of Brod to produce high levels of IL-10 and significant levels of other cytokines, Applicants believe the cited reference fails to anticipate Claim 1, and dependent Claims 2-7, and 10-13. Applicants submit

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that new Claim 19 is free from this basis of rejection, as the cited reference does not teach differentiation of an isolated or purified cord blood T cell.

Applicants submit that the rejection of Claims 1-7, and 10-13, under 35 U.S.C. §102(e) is overcome by the foregoing amendment. Withdrawal of this rejection is respectfully requested.

### Conclusion

Applicants' current response is believed to be a complete reply to all the outstanding issues of the latest Office action. Further, the present response is a bona fide effort to place the application in condition for allowance or in better form for appeal. Accordingly, Applicants respectfully request reconsideration and passage of the amended claims to allowance at the earliest possible convenience.

Applicants believe that no fees are due with this communication. Should this not be the case, the Commissioner is hereby authorized to debit any charges or refund any overpayments to DNAX Deposit Account No. 04-1239.

If the Examiner believes that a telephonic conference would aid the prosecution of this case in any way, please call the undersigned.

Respectfully submitted,

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By: Sheela Mohan-Peterson  
Sheela Mohan-Peterson  
Registration No.: 41,201  
Attorney for Applicants

**Customer No. 028008**  
DNAX Research, Inc.  
901 California Avenue  
Palo Alto, CA 94304-1104  
Tel. (650) 496-6400  
Tel. (Direct): (650) 496-1244  
Fax: (650) 496-1200

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